METHOD FOR ANALYSIS OF COMPLEX RHYTHM DISORDERS

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 14/062,848, filed Oct. 24, 2013, issued Sep. 16, 2014, as U.S. Pat. No. 8,838,223, which is a continuation of U.S. application Ser. No. 13/964,604, filed Aug. 12, 2013, which is a continuation of U.S. application Ser. No. 12/576,809, filed Oct. 9, 2009, issued Aug. 27, 2013, as U.S. Pat. No. 8,521,266, which claims the benefit of the priority of provisional application 61/195,866, filed Oct. 9, 2008, each of which is herein incorporated by reference in its entirety.

GOVERNMENT RIGHTS

This invention was made with government support under Grants HL070529 and HL083359 awarded by the National Institutes of Health. The government has certain rights in the invention.

FIELD OF THE INVENTION

This invention relates generally to the field of medicine and more specifically to a method, system and machine for diagnosing, finding the source for and treating irregularities and other disorders of biological rhythms. In particular, the present invention can be applied to minimally invasive techniques or surgical techniques to detect, diagnose and treat the disorder. One embodiment directs this invention to disorders of heart rhythm, another to electrical disorders of the brain and nervous system and others to electrical or contractile disorders of the smooth muscle of the gastrointestinal and genitourinary systems.

BACKGROUND OF RELATED ART

Heart rhythm disorders are very common in the United States, and are significant causes of morbidity, lost days from work, and death. Heart rhythm disorders exist in many forms, of which the most complex and difficult to treat are atrial fibrillation (AF), ventricular tachycardia (VT) and ventricular fibrillation (VF). Other rhythms are more simple to treat, but may also be clinically significant including atrial tachycardia (AT), supraventricular tachycardia (SVT), atrial flutter (AFL), premature atrial complexes/beats (SVE) and premature ventricular complexes/beats (PVC). Under certain conditions, rapid activation of the normal sinus node can cause the heart rhythm disorder of inappropriate sinus tachycardia or sinus node reentry.

Treatment of heart rhythm disorders, particularly the complex ones of AF, VF and VT, can be very difficult. Pharmacologic therapy is particularly suboptimal for AF (Singh, Singh et al. 2005) and VT or VF (Bardy, Lee et al. 2005) and, as a result, there is considerable interest in non-pharmacologic therapy. Ablation is a promising and increasingly used therapy to eliminate heart rhythm disorders by maneuvering a sensor/probe to the heart through the blood vessels, or directly at surgery, then delivering energy to the cause(s) for the heart rhythm disorder to terminate it. Ablation was initially used for "simple" disorders such as SVT. AFL. PVC, PAC, but is increasingly used for AF (Cappato, Calkins et al. 2005). VT (Reddy, Reynolds et al. 2007) and, to a lesser extent, VF (Knecht, Sacher et al. 2009).

However, ablation is often difficult because tools to identify and locate the cause of the heart rhythm disorder are poor, hindering attempts to deliver energy to the correct region to terminate and eliminate the disorder. In persistent AF, a highly prevalent form of AF, ablation has a one procedure success rate of only 50-60% (Cheema, Vasamreddy et al. 2006; Calkins, Brugada et al. 2007) despite lengthy 4-5 hour procedures and a 5-10% rate of serious complications (Ellis, Culler et al. 2009) including death (Cappato, Calkins et al. 2009). Even for 'simple' disorders such as atrial tachycardia, tools do not exist to make the diagnosis and suggest a likely successful ablation location.

Even the most sophisticated known systems display data that the practitioner has to interpret, without directly identifying and locating the cause of the disorder to enable the practitioner to detect, diagnose and treat it. This includes currently used methods, described in U.S. Pat. No. 5,662,108, U.S. Pat. No. 5,662,108, U.S. Pat. No. 6,978,168, U.S. Pat. No. 7,289,843 and others by Beatty and coworkers, U.S. Pat. No. 7,263,397 by Hauck and Schultz, U.S. Pat. No. 7,043,292 by Tarjan and coworkers, U.S. Pat. No. 6,892,091 and other patents by Ben-Haim and coworkers and U.S. Pat. No. 6,920,350 by Xue and coworkers. These methods and instruments detect, analyze and display electrical potentials, often in sophisticated 3-dimensional anatomic representations, but still fail to identify and locate the cause of heart rhythm disorders, particularly for complex disorders such as AF. This is also true for patents by Rudy and coworkers (U.S. Pat. Nos. 6,975,900 and 7,016,719, among others), which use signals from the body surface to "project" potentials on the heart.

Certain known methods for identifying and locating causes for heart rhythm disorders may work in simple rhythm disorders, but there are no known methods that have been successful with respect to identifying causes for complex disorders such as AF. VF or polymorphic VT. Activation mapping (tracing activation back to the earliest site) is useful only for simple tachycardias, works poorly for AFL (a continuous rhythm without a clear "start"), and not at all for AF with variable activation paths. Entrainment mapping uses pacing to identify sites where the stimulating electrode is at the cause of a rhythm, yet pacing cannot be applied in AF and even some "simple" rhythms such as atrial tachycardias due to automatic mechanisms. Stereotypical locations are known for the cause(s) of atrioventricular node reentry, typical AFL and patients with early (paroxysmal) AF, but not for the vast majority of patients with persistent AF (Calkins, Brugada et al. 2007), VF and other complex disorders. Thus, no methods yet exist to identify and locate the cause of complex heart rhythm disorders such as AF (Calkins, Brugada et al. 2007).

As an example of systems for "simple" rhythms with consistent activation from beat to beat is given by U.S. Pat. No. 5,172,699 by Svenson and King. This system is based upon finding diastolic intervals, which can be defined in "simple rhythms," but no complex rhythms such as atrial fibrillation (AF) or ventricular fibrillation (VF) (Calkins, Brugada et al. 2007; Waldo and Feld 2008). Moreover, this system does not identify or locate a cause, since it is examines diastolic intervals (between activations) rather than activation itself. In addition, it is focused on ventricular tachycardia rather than AF or VF, since it analyzes periods of time between QRS complexes on the ECG.

Another example is U.S. Pat. No. 6,236,883 by Ciaccio and Wit. This invention uses a concentric array of electrodes to identify and localize reentrant circuits. Accordingly, this will not find non-reentrant causes such as focal beats.